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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,012	07/23/2003	Gustave Bergnes	7144PI	9951
22852	7590	03/09/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			TRUONG, TAMTHOM NGO	
		ART UNIT		PAPER NUMBER
		1624		

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,012	BERGNES ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 1-13-06 (Election).
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) 7,10,12-14 and 17-22 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6,11,15,16 and 23 is/are rejected.
 7) Claim(s) 8 and 9 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/1/04 ; 1/13/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group 2 (Claims 1-6, 8, 9, 11, 15, 16 and 23 (in part)) in the reply filed on 01-13-06 is acknowledged.

Claims 1-23 are pending.

Claims 7, 10, 12-14 and 17-22 are withdrawn from consideration as being drawn to the non-elected subject matter.

Only claims 1-6, 8, 9, 11, 15, 16 and 23 (in part) are considered herein.

Specification

1. The disclosure is objected to because of the following informalities:

Page 16, the paragraph [053], the name for formula IIA (see the last line of paragraph [053]) is inconsistent with the structure. The name has the substituent of “*2-oxo-hexahydro-piperidin-4-yl*” while the structure has the substituent of “*2-oxo-hexahydro-pyrimidin-4-yl*”

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6, 11, 15, 16 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. In claims 1 and 16, variables R[”] and R^{1-R¹⁰} represent substituents that are “*optionally substituted*” which renders those claims indefinite because in the absence of the specific moieties intended to effectuate modification by “substitution” or attachment to the chemical core claimed, the phrase “*optionally substituted*” renders the claims in which it appears indefinite in all occurrences wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.
- b. Claims 1 and 16 recite the term “*solvate*” which has indefinite metes and bounds because it is unclear what solvent and its proportion are intended.
- c. Claim 6 lacks antecedent basis because it depends on claim 1, but recites variable V as “N(*optionally substituted amino-lower alkyl*)”, which is not recited in claim 1.
- d. Claims 15 and 23 recites the phrase of “a cellular proliferative disease” which has indefinite metes and bounds because it is unclear what other diseases (besides cancers) are intended by such a phrase. Furthermore said phrase reads on *embryogenesis*, and thus it is unclear if the kit is intended for contraception or abortion.
- e. Claims 2-6, 11, 15, 16 and 23 are rejected as being dependent on claim 1 or 16, and carrying out the indefinite limitations.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Lack of Written Description:** Claims 1-6, 11, 15, 16 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 16 recite the term “*solvate*” which is only briefly defined as “*a compound ... in physical association with one or more molecules of a pharmaceutically acceptable solvent.*” The specification fails to describe which solvent is suitable for forming a *solvate*, and in what proportion. For the claimed compound, there is no reference teaching any possible *solvate*. Because the process of making a “*solvate*” is quite unpredictable, it is not possible to predict whether a solid solution will form and at what stoichiometry proportion (i.e, one, two, or half a molecule of solvent added per molecule of host). Thus, the limitation of “*solvate*” does not have adequate written description in the specification or state of the prior art, particularly the reference of **Chenard et. al. (US 6,627,755 B1)** cited on PTO-892.

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Claim Objections

4. Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims only recite quinazolinone species substituted with “2-*oxo-hexahydro-pyrimidin-4-yl*”, which are not taught or fairly suggested by the prior art of record.

Information Disclosure Statement

5. The IDS of 1-13-06 and 11-01-04 have been fully considered. Both IDS's provide a total of 345 references. Applicant is reminded to bring to the examiner's attention the most relevant reference from such an extensive list. See the following excerpt from M.P.E.P 2004:

13. It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F. Supp. 948, 175 USPQ 260 (S.D. Fla. 1972), *aff'd*, 479 F.2d 1338, 178 USPQ 577 (5th Cir. 1973), *cert. denied*, 414 U.S. 874 (1974). But cf *Molins PLC v. Textron Inc.*, 48 F.3d 1172, 33 USPQ2d 1823 (Fed. Cir. 1995).

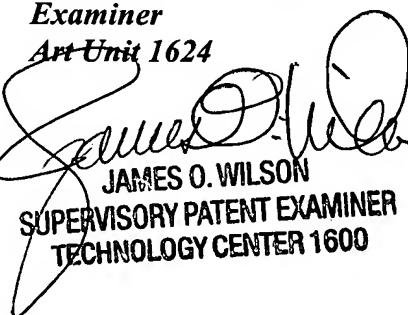
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3-6-06


Tamthom N. Truong
Examiner
Art Unit 1624

James O. Wilson
SUPERVISORY PATENT EXAMINER
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